



Supplements...Know the Dangers

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- A SGT suffered heat stroke & severe muscle damage on mile 10 of a unit road march
- A SPC was diagnosed with an irregular heartbeat after she collapsed during a run at Airborne School
- A PFC died during a physical fitness test

Objectives...



- Why supplements?
- Dangerous ingredients
- What's on the market
- Labeling
- What the FDA has to say

Why supplements??



- Lose weight
- Speed metabolism
- Improve performance
- Increase muscle mass
- More energy
- All of the Above!!!
- “Other” Reasons
- Euphoria
- Increased sexual sensations
- Heightened awareness
- Increased energy

Ephedrine Alkaloids

- **Ephedrine...most common**
- Pseudoephedrine
- Norpseudoephedrine
- Norephedrine
- Methylephedrine
- Methylpseudoephedrine



Ephedrine Alkaloids

- Amphetamine-like compounds
- Powerful stimulant effects on the CNS & CVS
- Stimulates receptors in the CNS & releases NE from body stores
- Repeated dosing depletes stores & decreases efficacy of ephedrine
- Plant-derived or chemically synthesized

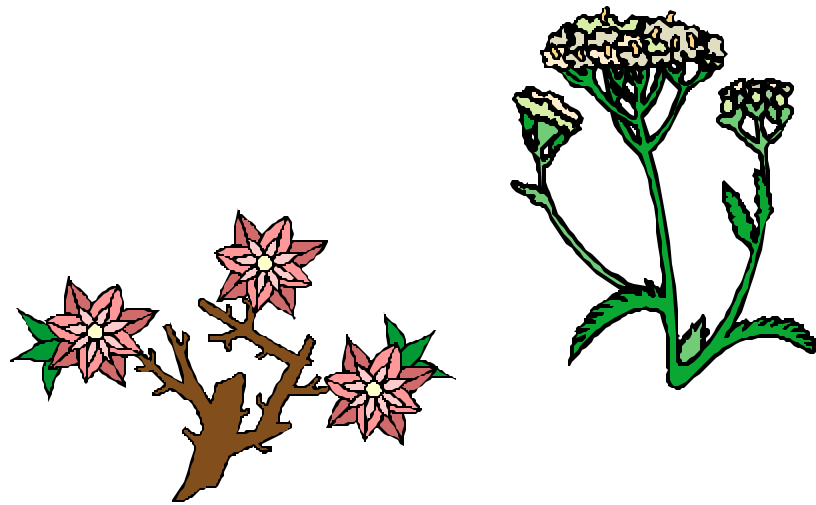
Mode of Action

- Ephedrine acts like the NTs epinephrine, norepinephrine, & dopamine
- Interact with receptors in the body that control the cardiovascular system & central nervous system
- CV & CNS effects of ephedrine last 10x longer than those with epinephrine
- Dopaminergic neuron damage similar to that caused by methamphetamines

“Natural Ephedra”

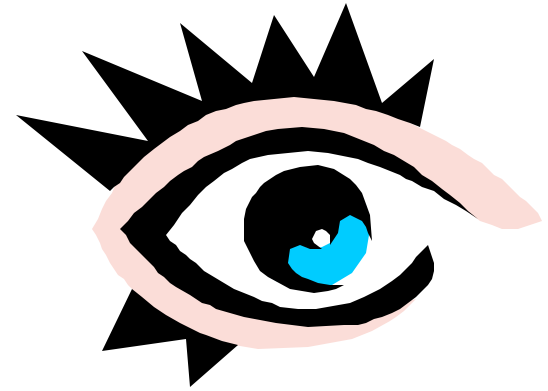
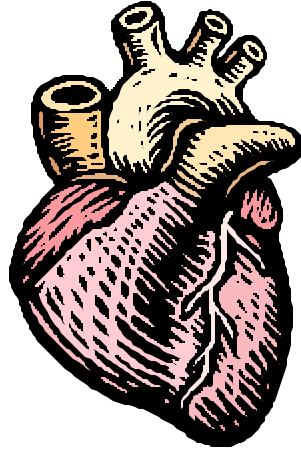
Herbal form in most supplements

- Ma Huang
- Chinese Ephedra
- Epitoinin
- Sida Cordifolia
- Ephedra sinica
- Ecstasy = street drug form
 - MDMA: methamphetamine analogue



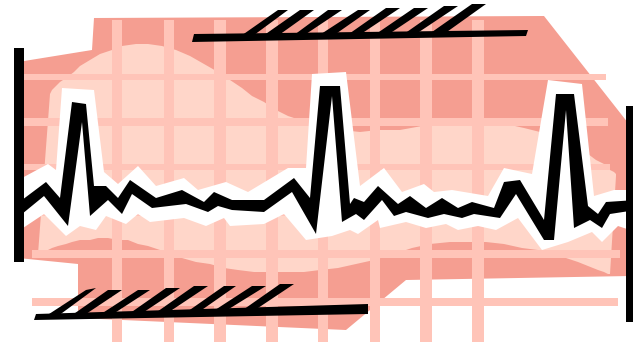
Organs Affected

- Eyes
- Liver
- Heart
- Kidneys
- Gastrointestinal Track
- Skeletal Muscle



Side Effects

- Tingling
- Tremors
- Seizures
- Hyperactivity
- Nervousness
- Heart palpitations
- Hepatitis
- Depression
- Skin flushing
- Irritability
- Insomnia
- Headache
- Dizziness
- GI distress



- Psychosis
- Blindness
- Heart attacks
- Strokes
- Chest Pain
- Increased blood pressure
- Heart rate irregularities
- Urinary tract infection
- Acute renal failure
- Urinary retention
- Cardiomyopathy

Side Effects

Death!!

Reported Illnesses

- Since 1993, over 800 reports of illnesses and injuries
- Approximately 14,775 “comments” from users & distributors
- AERs associated with the use of >100 products containing ephedrine alkaloids
- Can occur with ≤ 10 mg ephedrine alkaloids

Side Effects

- Sensitivity to side effects increases with...
 - Chronic use
 - Repeated pattern of starting & stopping use
- Most adverse reactions stop after discontinuing the product
- Most don't need medical treatment

Most events occurred in young to middle aged otherwise healthy adults

📦 92% AERs = weight loss/energy purposes

📦 5% AERs = athletic performance or body building

📦 59% occur <4 weeks of use

📦 60% after 7 days of use

📦 40% 1st use or 1st week of use

📦 14% occur 1st day of use

📦 56% = under age 40

📦 25% = age 40-49

📦 75% = women using for weight loss

- Hypertension, especially if overweight
- Heart conditions
- Eating disorder...bulimia or anorexia
- Pregnant &/or breastfeeding women
- Depressive or anxiety disorder
- Thyroid disease
- Genetics
- Disease history
- History of drug use
- Using other medications...antihistamines, antidepressants (takes 2 weeks to clear an MAOI)

**Stimulants *MOST*
dangerous in
individuals with...**

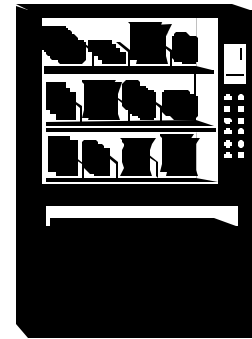
Product Information

- >125 ephedra products
- 0-110 mg ephedrine alkaloids per serving
- Most = 10 mg/serving
- <8mg to cause side effect
- Most...NOT all, bare warning statements

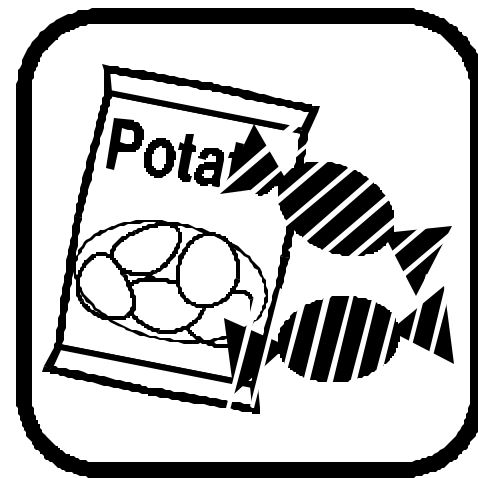




Conventional Foods



- Form: capsules, tablets, powders, liquids, cookies, snack bars
- Ephedrine alkaloids are unapproved food additives when used in “conventional foods”



Up to 20 Other Ingredients

Dangers of *Synergism*!!

- Caffeine: Guarana, Kola nut, Yerba mate
- White willow: Salicin or Aspirin
- “Stack” = Ephedrine, Caffeine, Aspirin
- Uva ursi (diuretic)
- Senna (laxative)
- St. John’s Wort (antidepressant)
- Vitamins & minerals
- HCA (Hydroxycitric Acid)
- PPA (phenylpropanolamine)
- 5-HTP (Hydroxytryptophan)
- Yohimbine
- DHEA
- Amino acids
- Ginseng
- Chitosan
- Chromium
- L-Carnitine
- L-Phenylalanine
- Pyruvate
- L-Tyrosine



What About the “Studies”

- Very small groups (<150)
- Frequent drop-outs due to adverse side effects
- Short duration (6-8 weeks)
- Physician monitored
- Controlled dosages (72-150 mg per day)
- Not using other meds concurrently
- Adverse effects still occurred, even when closely monitored & were in good health prior to study

Problem with Soldiers

- Don't know **how** to read labels
- Don't **choose** to read labels
- Product labeling is not standardized anyway
- May take with caffeine, antihistamines
- May take with ephedra bar or beverage
- Take for longer periods than recommended
- Don't know if at risk for an adverse effect
- Combine with unfamiliarly intense exercise



- These products are supplements therefore not under stringent regulation as are drugs.
- Because these products are marketed as supplements, there is little to no premarket review by the FDA of safety or effectiveness
- The FDA has to act product-by-product and the legal burden is on the FDA to show that a marketed product is unsafe, rather than on the company to gain FDA approval by showing the product is safe before marketed.

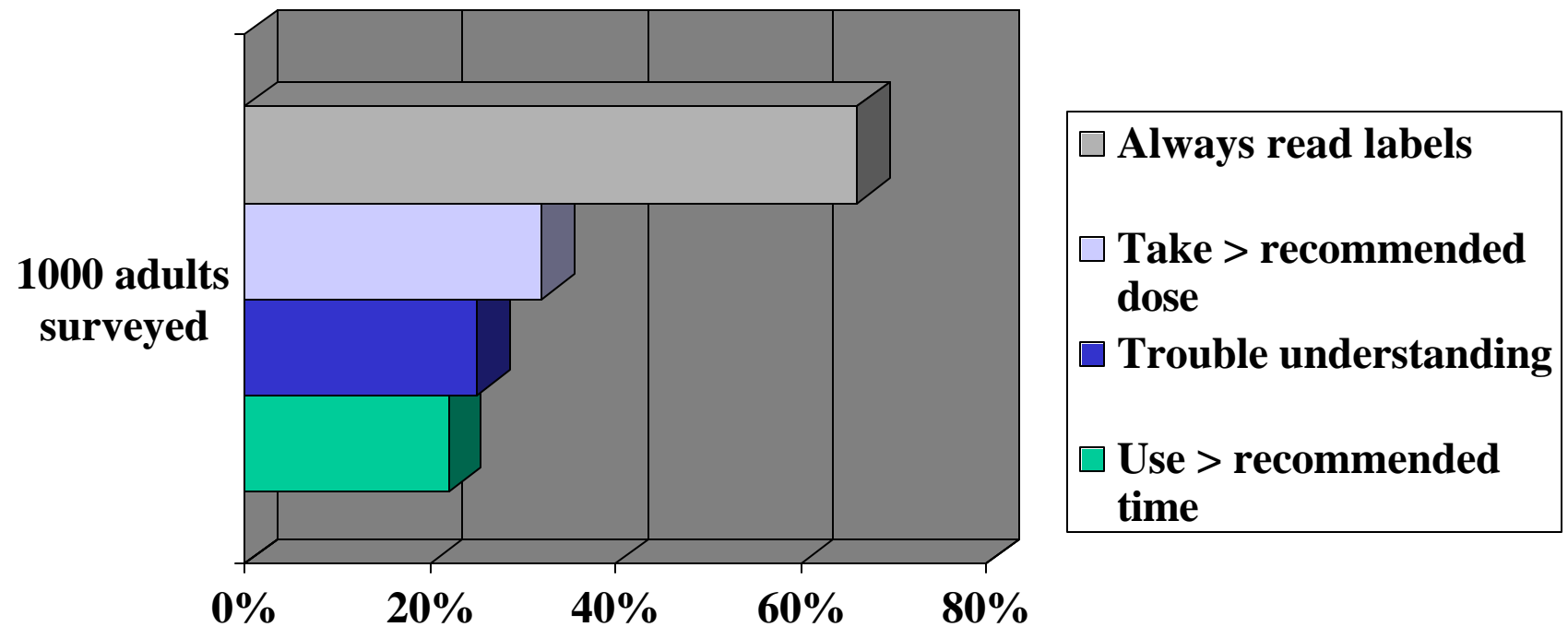
FDA Proposal 4 June 1997

- Product is considered *adulterated* if...
 - >8 mg ephedrine alkaloids per serving
 - Label suggests >8 mg be taken within a 6-hour period
 - Total daily intake of 24 mg or more
 - Label does not caution against using it for more than 7 days.

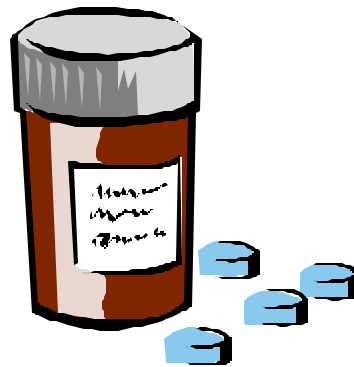
Faulty Labeling??

- “Take what your body needs.”
- “Take 1 tablet (7mg) per serving, not to exceed 3 tablets per day.”
- “Take 1 tablet per day.”
- “Take 1 tablet every 6 hours, do not take more than 3 tablets per day.”
- “Take 1 tablet not more than every 8 hours, do not take more than 2 tablets per day.”

More on Labeling



“Energy enhancement” products
should be required to bear a label
stating that “taking more than the
recommended serving may result in
heart attack, stroke, seizure, or death”





Problem with 7 Days

Weight loss & body building are long-term activities & require a long-term solution



OTC/Prescription Meds

Proposal does not cover OTC or prescription drugs containing ephedrine alkaloids although the Department of Justice DEA requested the restriction of OTC availability of ephedrine (bronchodilator products) because of its illicit use as the primary precursor in the synthesis of the controlled substances **methamphetamine & methylcathinone**.

What can you do?

Consumers who have been injured or suffered an adverse effect after taking a dietary supplement containing ephedra should call:

1-800-FDA-4010

WEB

- <http://vm.cfsan.fda.gov>
- <http://odp.od.nih.gov/ods>
- <http://www.cfsan.fda.gov>
- <http://www.gssiweb.com>

